REMARKS

In the Office Action dated June 16, 2005, claims 1-6 and 10-13 were rejected under 35 U.S.C. §102(e) as being anticipated by Fishler. Claims 7-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Fishler, further in view of Van Dam et al. Claim 14 was rejected under 35 U.S.C. §103(a) based on the teachings of Fishler, Van Dam et al and Bradley.

These rejections are respectfully traversed for the following reasons. Claim 1 as originally filed required "a further electrode connected to said control circuit and adapted for positioning in the subject *at a distance from the heart*" (emphasis added). Moreover, original dependent claim 10 stated that the control circuit employs the housing as an electrode, in combination with the further electrode, for sensing the intracorporeal ECG signal. Original claim 12 included at least one electrode dot disposed on the housing, and stated that the control circuit uses this electrode dot, in combination with the further electrode, for sensing the intracorporeal ECG signal. In view of dependent claims 10 and 12, which clearly state that a housing, or a dot on the housing, is used "in combination with said further electrode," it is clear that the further electrode cannot be formed by the housing, otherwise dependent claims 10 and 12 would not make sense. Nevertheless, independent claim 1 has been amended to explicitly state that the further electrode is remote from the housing.

No such further electrode that is remote from the housing is disclosed or suggested in the Fishler reference. In the substantiation of the anticipation rejection based on Fishler, the Examiner referred to the housing in Fishler as serving as an electrode that is positioned at a distance from the heart. For the reasons noted

above, claim 1 even in the form as originally filed should not have been interpreted to encompass the possibility of the further electrode being the housing, because this would then have rendered original dependent claims 10 and 12 as unintelligible. It is not permissible to interpret a claim in a manner that renders that claim, or any other claim in the application, inoperative or unintelligible, if an interpretation is available that makes all of the claims consistent with each other. As noted above, interpreting claim 1 as originally filed so that the further electrode is not the housing renders all of the claims as internally consistent. Moreover, claim 1 as originally filed included the housing as a separate claim element, and if the further electrode were interpreted as being the housing, this would mean that the same element had been included twice in claim 1.

Aside from this structural distinction between the subject matter of claim 1 and the disclosure of the Fishler reference, there is an important functional or operational distinction as well. The Fishler reference refers to the term "threshold" at two different locations, and Applicant submits it is clear to a person of ordinary skill in the field of cardiac pacing that the term "threshold" at those respective locations is being used in a different context, and with a different meaning, at each location. The Examiner has correctly noted that Fishler defines the lowest pulse energy required to achieve capture as "threshold" at column 1, lines 50-54. The Examiner also noted that Fishler teaches the use of sensing circuits that employ amplifiers with programmable gain, and a threshold detection circuit (column 7, lines 6-10).

The term "threshold" associated with capture refers to an energy that must be *delivered* or *output* in order to achieve capture. The "threshold detection circuit" associated with the sensing amplifiers refers to the ability of the sensing circuit to

detect electrical activity of the heart at a particular level. In general, the use of the term "threshold" associated with capture refers to the energy content of a signal that is *outgoing* from a pacemaker, whereas the use of the term "threshold" in association with sensing circuitry refers to a signal that is *incoming* to the pacemaker. Sometimes, in order to avoid such confusion, the "threshold" that is associated with the detection circuitry is referred to as the "sensing threshold".

Evidence that these terms are differently used in the context of capture and in the context of detection, and that these terms and the difference therebetween are well known to those of ordinary skill in the art, is provided by the attached excerpt from *A Practical Guide to Cardiac Pacing, Fourth Edition*, Moses et al, (page 208) wherein "sensing threshold" and "threshold" are defined in the glossary as described above, and the excerpt from *Cardiac Rhythm Management Glossary*, published by St. Jude Medical (page 97) which provides both definitions for the term "threshold."

Therefore, in the Fishler reference it is clear that the sensing circuitry, despite having a programmable threshold, does not sense, via the further electrode, at least one intracorporeal ECG signal, and does not analyze at least one characteristic in the intracorporeal ECG signal to determine whether a loss of capture has occurred on either of the first or second electrodes.

As the Examiner has noted, the Fishler reference does disclose the use of morphology analysis of the QRS complex for making various conclusions, however, this QRS complex is not obtained in the Fishler reference via a "further electrode" that is not only remote from the housing, but also is adapted for positioning in the subject at a distance from the heart.

It is true that the Fishler reference, in some embodiments, teaches acquiring the signal representing the QRS complex between a tip electrode and a ring electrode carried by the same endocardial lead, however, if this embodiment is used, both the tip electrode and the ring electrode are placed in a ventricle. As set forth in claim 13 of the present application, it is possible for the further electrode to be a ring electrode that is disposed on the same endocardial lead as one of the first or second electrodes (forming a tip electrode for that lead). If this embodiment of the present invention is utilized, however, the ring electrode is still placed at a distance from the heart, as indicated by ring electrodes 9 and 10 shown in Figure 4 of the present application.

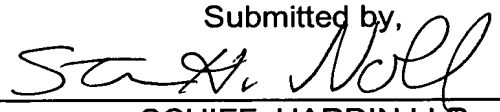
The Fishler reference, therefore, does not disclose all of the elements of claim 1 as arranged and operating in that claim, and therefore does not anticipate claim 1, nor any of the claims depending therefrom.

The Van Dam et al reference does not provide any teachings or suggestions regarding the use of such a further electrode that is remote from the housing and adapted to be placed in the subject at a distance from the heart, with an intracorporeal ECG signal obtained via that further electrode being analyzed to assess whether a loss of capture has occurred on either of the first or second ventricular leads. Therefore, even if the Fishler reference were modified in accordance with the teachings of Van Dam et al, the subject matter of claims 7-9 still would not result. Claims 7-9, therefore, would not have been obvious to a person of ordinary skill in the field of cardiac pacemaker design based on the teachings of Fishler and Van Dam et al.

The Bradley reference does not add any further teachings on this point to the Fishler/Van Dam et al combination, and therefore even if the Fishler/Van Dam et al combination were further modified in accordance with the teachings of Bradley, the subject matter of claim 14 still would not result. Claim 14, therefore, would not have been obvious to a person of ordinary skill in the field of cardiac pacemaker design based on the teachings of those references.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,



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